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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0207] (formerly Docket No. 2007D-0202)

Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions." The guidance explains FDA's current thinking on a number of microbiological issues unique to the preparation of premarket submissions for antimicrobial food additives.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-436-2972. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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FOR FURTHER INFORMATION CONTACT: Judith Kidwell, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 25, 2007 (72 FR 54446), FDA announced the availability of a draft guidance entitled “Guidance for Industry: Microbiological Considerations for Antimicrobial Food Additive Submissions.” FDA gave interested parties an opportunity to submit comments on the draft guidance by November 26, 2007. The agency considered the one received comment as it finalized the guidance. The guidance announced in this notice finalizes the draft guidance dated September 2007.

FDA is issuing this guidance document as level 1 guidance consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance document represents FDA’s current thinking on a number of microbiological issues unique to the preparation of premarket submissions for antimicrobial food additives. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection of information in 21 CFR 70.25, 71.1, 170.35, and 171.1 have been approved under OMB

control number 0910–0016; the collection of information in 21 CFR 170.39 has been approved under OMB control number 0910–0298; and the collection of information in 21 CFR 170.101 and 170.106 have been approved under OMB control number 0910–0495.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.cfsan.fda.gov/guidance.html*.

Dated: 6/19/08
June 19, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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